K113376

SEP 5 2012

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Neoss Tapered Implant 510(k) premarket notification.

Sponsor:

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Alexandria, VA 22314
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Manufacturing:

Implants
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SE-540 16 Timmersdala, Sweden.
Registration Number: 3003847101

Elos Medtech Pinol AS
Engsvej 33
DK-3330 Gorlose, Denmark.
Registration Number: 3007689689

Packaging Facility
Wesley Coe Ltd
Gas Lane
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CB7 4GH, UK
Registration Number: 8044131

Sterilization Facility
Swann-Morton Ltd
Owlerton Green
Hillsborough,
Sheffield, S6 2BJ, UK
Registration Number: 9611194

Date of Submission: November 14, 2011

Proprietary Name: Neoss Tapered Implant

Common Name: Dental implant

Regulatory Class: Class II

Product Codes: DZE

Regulation: 872.3640 Implant, Endosseous, Root Form

Predicate Device(s): Neoss Proactive Implant (K083561)

Device Description:

The Neoss Tapered Implant is a threaded, internal abutment connection, root-form titanium dental implant. The Neoss Tapered Implant consists of a number of implants with a diameter of Ø3.5 to Ø5.5 mm and lengths between 7.0 – 17.0 mm; all sizes have the same internal abutment connection dimension independent of implant diameter.

The internal connection is equipped with interlocking elements for an insertion tool and the non-rotational locking of the abutment. The Neoss ProActive Tapered Implant System is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices, which can restore chewing function and aesthetic appearance. Supplied sterile.

The Neoss Implant System has specific design characteristics for mating Neoss components such as implants, abutments and prosthetic components. Combining components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory esthetic results. Abutment screws made in gold alloy, titanium or Ti with TiN/Au are available. Screw driver connection is compatible with screwdrivers supplied by Neoss. The abutment screws are supplied non-sterile.

Indication for Use:

The Neoss Tapered Implant is for single-stage or two-stage surgical procedure and cement or screw retained restorations.

The Neoss Tapered Implant is intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Summary of Technological Characteristics:

The line extension to the Neoss ProActive Implant includes an assortment of tapered sizes. Tapered designs more closely reflect the shape of the tooth root. In animal testing, grit-blasted and acid-etched surfaces exhibit an increase in the strength of osseointegration when compared to machined surfaces. Additionally, in animal testing, grit-blasted and acid-etched surfaces exhibit an increased bone to implant contact when compared to grit-blasted surfaces.

Summary of Performance Testing:

Performed fatigue tests of ProActive implants (K083561) shows results well in line with requirements. Clinical feedback and only one fracture related complaint confirms that the implant strength is adequate. The design in critical areas shows enough similarity between the two implant types to conclude that Neoss Tapered Implants will show equivalent results as for ProActive Implants in a fatigue test.

The Neoss Tapered Implant has an enhanced primary stability, i.e. mechanical stability at time of insertion as measured by in vitro insertion, displacement, and theoretical implant-bone contact analysis, compared to a straight Neoss implant. This testing of primary stability and long term clinical outcome has not been correlated.

Conclusion:

The modified Neoss Tapered Implant has the following similarities to the Neoss ProActive Implant previously cleared in K083561:

- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials,
- incorporates the same surface characteristics and
- has similar packaging and is sterilized using the same materials and processes

Therefore the modification to the Neoss Tapered Implant can be found substantially equivalent to the Neoss ProActive Implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 5 2012

Neoss Limited
C/O Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K113376
Trade/Device Name: Neoss Tapered Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 20, 2012
Received: August 22, 2012

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113376

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: Neoss Tapered Implant

Indications for Use: The Neoss Tapered Implant is for single-stage or two-stage surgical procedure and cement or screw retained restorations.

The Neoss Tapered Implant is intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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